MAIL STOP APPEAL BRIEF-PATENTS
PATENT
1501-1317

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of:	Appeal No.
Tomas FABO	Conf. 9965
Application No. 10/553,953	Group 1611
Filed June 12, 2006	Examiner Kevin Orwig

ELASTOMER-FORMING BARRIER PREPARATION

APPEAL BRIEF

MAY IT PLEASE YOUR HONORS: February 16, 2010

(i) Real Party in Interest

The real party in interest in this appeal is the Assignee, MÖLNLYCKE HEALTH CARE AB of Göteborg, Sweden.

(ii) Related Appeals and Interferences

Neither the appellant, appellant's legal representative nor the assignee know of any other prior or pending appeals, interferences or judicial proceedings which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(iii) Status of the Claims

Claims 1-20 remain in this application. Claims 1-8, 17 and 18 have been withdrawn from consideration. Claims 9-16, 19 and

20 are under consideration, whose final rejection this appeal is taken.

(iv) Status of Amendments

There are no outstanding amendments. The claims have not been amended since the March 16, 2009 amendment. These claims were finally rejected by the Official Action mailed May 19, 2009 (the "Official Action"). The claims are as set forth in the Claims Appendix.

(v) Summary of Claimed Subject Matter

The independent claim is claim 9, which is directed to a method for applying a protective layer to non-wounded skin (stratum corneum), comprising:

(See, e.g., specification page 6, lines 16-17 in view of page 7, lines 5-6.)

applying a preparation comprising a silicone composition, which is highly viscous on application and which, after application, cures, by means of crosslinking, to form a soft and skin-friendly elastomer which adheres to non-wounded skin, and

(See, e.g., specification page 6, lines 18-23 in view of page 7, lines 5-6.)

allowing the preparation to cure to form a soft, skin-friendly elastomer which adheres to the non-wounded skin.

(See, e.g., specification page 6, lines 24-25 in view of page 7, lines 5-6.)

(vi) Grounds of Rejection to be Reviewed on Appeal

There are two grounds of rejection to be reviewed on appeal, namely:

1) Whether claims 9, 10 and 14 were properly rejected under 35 U.S.C. §103(a) as being unpatentable over GUYURON et al. U.S. 6,471,985 (GUYURON).

2) Whether claims 9, 11-13, 15, 16, 19 and 20 were properly rejected under 35 USC 103(a) as being unpatentable over GUYURON in view of ABBER et al. U.S. 4,925,671 (ABBER).

(vii) Arguments

1) None of claims 9, 10 and 14 is unpatentable over GUYURON.

A number of the claims subject to this ground of rejection are argued separately, per the subheadings that follow.

Claims 9 and 10

Independent claim 9 is directed to a method of applying a protective layer to non-wounded skin (stratum corneum) comprising applying a preparation which adheres to non-wounded skin, and allowing the preparation to cure to form an elastomer which adheres to the non-wounded skin.

The present specification (at page 16, lines 30-34) describes that the risk for the preparation to spread into the wound is reduced. Indeed, as explained at page 7, lines 5-6, the preparation is applied around the wound. Thus, in view of the claimed language, especially when read in light of the specification, it is clear that the claimed method applies the preparation to non-wounded skin.

GUYURON teaches a method of treating wounds utilizing a room temperature vulcanizing (RTV) silicone composition. The rejection is based on the following assumption, as explained in the paragraph bridging pages 3 and 4 of the Official Action:

> "Since an object of Guyuron's invention is to prevent infection of the wound (col. 1, lines 19-23 and 62-63; col. 2, lines 49 and 58), an ordinary artisan would understand Guyuron's teachings to mean that the silicone composition is applied over a wound, including the surrounding non-wounded skin as is typical of methods aiming to prevent infection by sealing a wound in order to prevent the entrance of bacteria or other contaminants."

However, this conclusion includes factual and legal errors.

a. There is no explicit teaching of applying a protective layer to non-wounded skin.

The disclosure of GUYURON is limited to applying a composition to a wound.

For example, GUYURON discloses treating wounds by applying a composition over the wounds. See, e.g., column 1, lines 6-8. The claims of GUYURON are limited to applying the composition to a wound.

In describing the prior art, GUYORON states "Wound dressings must adhere to a wound, yet possess releaseability characteristics enabling a non-damaging removal from the wound." See, e.g., column 1, lines 25-28.

Moreover, GUYURON discloses, in column 11, lines 6-9, "The RTV silicone composition may be custom fit to any contoured or shaped surface. This advantage over and in contrast with prefabricated bandaids or dressings, or dressings that must be cut and fit to a wound." (Emphasis added.)

Thus, in light this discussion, both GUYURON and the relevant prior art are solely focused on application to the wound itself. There is no mention of the non-wounded skin (stratum corneum), i.e., around the wound itself.

b. There is no implicit teaching or suggestion of applying a protective layer to non-wounded skin.

The conclusion on page 8, first paragraph of the Official Action states, "there would be at least some amount of wounded tissue left unprotected between the composition and the non-wounded skin". The support cited was column 1, lines 59 and 60 of GUYURON.

However, this passage cited in support of the conclusion merely states that the silicone adequately adheres to a wound, but says nothing about adherence to skin.

Moreover, GUYURON discloses that the advantage of applying the composition in a highly viscous state makes it possible to cover the whole wound bed. This is done without

having to apply the composition to non-wounded skin surrounding the wound bed.

Even if some composition unintentionally reached outside the wound bed, this contact would not teach the claimed method of applying a protective layer to non-wounded skin (stratum corneum), e.g., comprising applying a preparation which adheres to non-wounded skin, and allowing the preparation to cure to form an elastomer which adheres to the non-wounded skin, as recited in independent claim 9.

c. GUYURON teaches away from the claimed method.

GUYURON, as discussed above, discloses that the composition "may be custom fit to any contoured or shaped surface", and the advantage over the prior art is that the dressings do not have to be cut and fit to a wound.

GUYURON requires that the composition forms a membrane over the wound to retain moisture in the wound. See, e.g., Column 11, lines 15-18.

Thus, one of ordinary skill in the art would have been discouraged from modifying GUYURON as claimed.

That is, application of a protective layer to non-wounded skin (stratum corneum) as recited in claim 9 would have rendered the composition GUYURON unsatisfactory for its intended purpose of fitting the wound and providing moisture retention.

If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose,

then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

In view of the above, it is believed to be apparent that the rejection of claims 9 and 10 based on GUYURON is improper and should be reversed.

Claim 14

Claim 14 depends from claim 9, and is separately patentable.

Claim 14 directed to applying the preparation around a wound, immediately outside the edge of the wound, with a width of 2-100 mm.

As noted above relative to claims 9 and 10, the conclusion of obviousness is based on factual and legal errors.

a. There is no explicit teaching of applying a protective layer around the edge of wound of a specific width.

The disclosure of GUYURON is limited to applying a composition to the wound itself, i.e., treating wounds by applying a composition over the wounds. See, e.g., column 1, lines 6-8. The claims of GUYURON are limited to applying the composition to a wound.

In describing the prior art, GUYORON states "Wound dressings must adhere to a wound, yet possess releaseability

characteristics enabling a non-damaging removal from the wound." See, e.g., column 1, lines 25-28.

Moreover, GUYURON discloses, in column 11, lines 6-9, "The RTV silicone composition may be custom fit to any contoured or shaped surface. This advantage over and in contrast with prefabricated bandaids or dressings, or dressings that must be cut and fit to a wound." (Emphasis added.)

Thus, GUYURON and the relevant prior art are solely focused on application to the wound itself. There is no mention of application immediately outside of the edge of the wound with a width of 2-100 mm.

b. There is no implicit teaching or suggestion of applying a protective layer to non-wounded skin.

The conclusion on page 8, first paragraph of the Official Action states, "there would be at least some amount of wounded tissue left unprotected between the composition and the non-wounded skin". The support cited was column 1, lines 59 and 60 of GUYURON.

However, this passage cited in support of the conclusion merely states that the silicone adequately adheres to a wound, but says nothing about adherence to skin.

Moreover, GUYURON discloses that the advantage of applying the composition in a highly viscous state makes it possible to cover the whole wound bed. This is done without having to apply the composition to non-wounded skin surrounding the wound bed.

Even if some composition unintentionally reached outside the wound bed, this contact would not teach or suggest that a protective layer is applied to non-wounded skin (stratum corneum) immediately outside of the edge of the wound with a width of 2-100 mm as recited in claim 14.

c. GUYURON teaches away from the claimed method.

GUYURON, as discussed above, discloses that the composition "may be custom fit to any contoured or shaped surface", and the advantage over the prior art is that the dressings do not have to be cut and fit to a wound.

GUYURON requires that the composition forms a membrane over the wound to retain moisture in the wound. See, e.g., Column 11, lines 15-18.

Thus, one of ordinary skill in the art would have been discouraged from modifying GUYURON as claimed.

That is, application of a protective layer to non-wounded skin immediately outside of the edge of the wound with a width of 2-100 mm would have rendered the composition GUYURON unsatisfactory for its intended purpose of fitting the wound and providing moisture retention.

If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

In view of the above, it is believed to be apparent that the rejection of claim 14 is based on GUYURON is improper and should be reversed.

2)None of claims 9, 11-13, 15, 16, 19 and 20 is unpatentable over GUYURON in view of ABBER

A number of the claims subject to this ground of rejection are argued separately, per the subheadings that follow.

Claims 9, 11-13, 19 and 20

For the reasons discussed above relative to the first ground of rejection, GUYURON fails to disclose or suggest the features of claim 9, from which claims 11-13, 15, 19 and 20 depend.

ABBER discloses specific devices that require adhesives with very specific characteristics: favorable adhesive, shear, liquid permeability and release characteristics.

The Examiner's position was that one would have envisioned the use of the composition taught by GUYURON as adhesives for the use suggested by ABBER.

However, to the contrary, one would have been discouraged from using the GUYURON adhesive with ABBER devices.

As the adhesive of GUYURON retains moisture when placed over a wound (e.g., as discussed in column 11, lines 15-18), the

adhesive would have rendered the ABBER devices requiring liquid permeability unsatisfactory for their intended purpose.

If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

In view of the above, it is believed to be apparent that the rejection of claims 9, 11-13, 19 and 20 based on GUYURON and ABBER is improper and should be reversed.

Claim 15 (and 14 from which it depends)

Claim 15 depends from claim 14. Claim 14 directed to applying the preparation around a wound, immediately outside the edge of the wound, with a width of 2-100 mm. However, the second ground of rejection does not include claim 14.

Claim 15 is believed to be separately patentable as it is directed to the application of one or more dressings to cover the wound and the area to which the preparation is applied (i.e., the width of 2-100 mm).

As discussed above relative to the first ground of rejection relative to claim 14, GUYURON fails to disclose or suggest applying the preparation around a wound, immediately outside the edge of the wound, with a width of 2-100 mm.

The Examiner's position was based on the use of the composition taught by GUYURON as adhesives for the use suggested by ABBER, i.e., for use with medical device. Thus, ABBER is not able to render the shortcomings of GUYURON for reference purposes with respect to the application of the preparation around the wound.

At best the combination teaches applying a medical device to a preparation, which over the wound itself, not to cover the wound and the 2-100 mm area immediately outside the wound to which the preparation is applied.

In view of the above, it is believed to be apparent that the rejection of claim 15 based on GUYURON and ABBER is improper and should be reversed.

Claim 16

Claim 16 depends from claim 15, and is directed to wound dressings that consist of liquid tight dressings. However, Claim 16 is also believed to be separately patentable.

The invention of GUYURON is directed to the application of a composition directly over the wound, which retains moisture (e.g., as discussed in column 11, lines 15-18).

The invention of ABBER is directed to specific devices that require adhesives to be, for example, liquid permeability.

The Examiner's position was based on the use of the composition taught by GUYURON as adhesives for the use suggested by ABBER.

Thus, as the devices of ABBER to be applied to the preparation have a specified liquid permeability, the combination fails to teach wound dressings that consist of liquid tight dressings.

In view of the above, it is believed to be apparent that the rejection of claim 16 based on GUYURON and ABBER is improper and should be reversed.

Conclusion

From the foregoing discussion, it is believed to be apparent that the rejections of claims 9-16, 19 and 20 are improper and should be reversed. Such action is accordingly respectfully requested.

Respectfully submitted,

YOUNG & THOMPSON

/Robert A. Madsen/
Robert A. Madsen, Reg. No. 58,543
209 Madison Street, Suite 500
Alexandria, VA 22314
Telephone (703) 521-2297
Telefax (703) 685-0573
(703) 979-4709

RAM/lad

(viii) **Claims Appendix**

The claims on appeal are:

1. (withdrawn) A preparation for applying to the skin (stratum corneum), characterized in that it comprises a silicone composition which is highly viscous on application and which, after application, cures, by means of crosslinking, to form a soft and skin-friendly elastomer which adheres to the skin.

2. (withdrawn) A preparation as claimed in claim 1, characterized in that, on application, it has a viscosity of 5-300 Pa*s, preferably 10-120 Pa*s, more preferably 20-80 Pa*s, and, after curing, has a penetration (softness) of 2-15 mm, preferably 3-10 mm.

3. (withdrawn) A preparation as claimed in claim 1, characterized in that, after curing on the skin, it has an adherence to the skin of 0.3-3.0 N/25 mm.

4. (withdrawn) A preparation as claimed in claims 1, characterized in that the curing time after application is 0.5 min-24 hrs, preferably 1 min-1 hr, more preferably 1-5 min.

5. (withdrawn) A preparation as claimed in claims 1,

characterized in that the preparation is hydrophobic.

6. (withdrawn) A preparation as claimed in claim 1,, characterized in that the silicone composition consists of an addition-curing RTV silicone system.

7. (withdrawn) A preparation as claimed in claim 6, characterized in that the crosslinkable substance in the silicone system consists of polydimethylsiloxane having some of its methyl groups replaced with vinyl groups and the crosslinking-forming substance consists of dimethysiloxane having some of its methyl groups replaced with hydrogen, and a platinum-based catalyst.

8. (withdrawn) A preparation as claimed in claim 6, characterized in that one or more skin-care substance(s) has/have been added to the silicone composition.

9. A method for applying a protective layer to non-wounded skin (stratum corneum), comprising:

applying a preparation comprising a silicone composition, which is highly viscous on application and which, after application, cures, by means of crosslinking, to form a soft and skin-friendly elastomer which adheres to non-wounded skin, and

allowing the preparation to cure to form a soft, skin-friendly elastomer which adheres to the non-wounded skin.

10. The method as claimed in claim 9, characterized in that the preparation is applied at a layer thickness of 0.1-5 mm.

11. The method as claimed in claim 9, wherein an article for medical use is applied to an upper side of the preparation, said upper side being a side which faces away from the skin, before the preparation has cured, with the article being affixed to the preparation after the latter has cured.

12. The method as claimed in claim 11, characterized in that the preparation is applied to the article for medical use before it is applied to the skin concurrently with the article.

13. The method as claimed in claim 11, characterized in that the preparation is designed such that its adherence to the article for medical use is greater than its adherence to the skin after curing.

14. The method as claimed in claim 9, characterized in that the preparation is applied around a wound, immediately outside

the edge of the wound, with a width of 2-100 mm.

15. The method as claimed in claim 14, characterized in that one or more wound dressing(s) is/are applied such that the dressing(s) cover(s) the wound and the area to which the preparation has been applied, with the dressing(s) being applied before the preparation has cured.

16. The method as claimed in claim 15, characterized in that the wound dressing(s) consist(s) of (a) liquid-tight dressing(s).

17. (withdrawn) A preparation as claimed in claim 2, characterized in that, after curing on the skin, it has an adherence to the skin of 0.3-3.0 N/25 mm.

18. (withdrawn) A preparation as claimed in claim 7, characterized in that one or more skin-care substance(s) has/have been added to the silicone composition.

19. The method as claimed in claim 10, wherein an article for medical use is applied to the upper side of the preparation, said upper side being a side which faces away from the skin, before the preparation has cured, with the article being affixed to the preparation after the latter

has cured.

20. The method as claimed in claim 12, characterized in that the preparation is designed such that its adherence to the article for medical use is greater than its adherence to the skin after curing.

(ix) **Evidence Appendix**

None.

(x) **Related Proceedings Appendix**

None.